K112791

FEB 2 4 2012

BARD
ACCESS SYSTEMS

510(k) Summary
21 CFR 807.92

General Provisions	Submitter Name: Address:	Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, UT 84116
	Contact Person: Telephone Number: Fax Number: Date of Preparation:	Lynn M. Kirchoff (801) 522-5636 (801) 522-5425 December 6, 2011
Subject Device	Trade Name: Common Name: Classification Name:	Site-Scrub IPA Device Pad, Alcohol, Device Disinfectant Unclassified, pre-amendment LKB
Predicate Devices	Trade Name: Classification Name: Premarket Notification: Manufacturer:	SwabCap Pad, Alcohol, Device Disinfectant K083508 Excelsior Medical Corporation (Neptune, NJ)
	Trade Name: Classification Name: Premarket Notification: Manufacturer:	Alcohol Prep Pad Pad, Alcohol, Device Disinfectant K833182 Aplicare, Inc. (Meriden, CT)
Device Description	The subject Site-Scrub IPA Device is a handheld, sterile, single use device containing isopropyl alcohol (IPA) 70% (v/v) solution. The Site-Scrub IPA Device, by design, provides active mechanical friction and IPA to clean and disinfect surfaces, such as injection ports and female luer hubs, in accordance with 2011 CDC guidelines that recommend for needleless intravascular catheter systems that contamination be minimized by "scrubbing the access port with an appropriate antiseptic (including 70% alcohol) and accessing the port only with sterile devices."[1] The foam design allows for application of the IPA on internal and external surfaces. The Site-Scrub IPA Device has been specifically designed to disinfect female luer hubs and injection ports and has undergone *in vitro* testing to validate its effectiveness for this purpose. The results of *in vitro*	

[1] 2011 Centers for Disease Control Guidelines for the Prevention of Intravascular Catheter-Related Infections. Accessed July 20, 2011, http://www.cdc.gov/hicpac/Disinfection_Sterilization/6_0disinfection.html.

Device Description Continued	antimicrobial efficacy testing show the Site-Scrub IPA Device is effective, when used as intended, for significantly reducing (> 4 Log_{10} or 99.99% reduction) microbial load of the following microbes known to be associated with catheter line-associated blood stream infections (CLABSI) which include[2]: 1. *Candida albicans,* 2. *Candida parapsilosis,* 3. *Escherichia coli,* 4. *Pseudomonas aeruginosa,* 5. *Staphylococcus aureus (MRSA), and* 6. *Staphylococcus epidermidis (MRSE).*
Indications for Use/Intended Use	The Site-Scrub IPA Device is intended for use on injection ports and female luer hubs as a disinfecting cleaner.
Technological Characteristics	Technological characteristics of the subject Site-Scrub IPA Device are equivalent with respect to the device's basic design and function to those of the predicate devices, Excelsior Medical's *SwabCap* and the Aplicare, Inc.'s *Alcohol Prep Pad.* The primary difference between SwabCap and the subject device is that the Site-Scrub IPA Device is not intended to act as a physical barrier to contamination between line accesses. Other technological characteristics of the subject device are comparable to the predicate devices. Distinguishing differences do not raise new questions regarding safety or efficacy of the subject device.
Safety & Performance Tests	Verification and validation tests have been performed in accordance with Design Controls as per 21 CFR §820.30. The following guidance documents and standards, in conjunction with internal protocols, were used to determine appropriate methods for evaluating the performance of the device: • *AAMI/ANSI/ISO 10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, and the FDA Modified ISO 10993 Test Profile* • *ISO 11137-1:2006, Sterilization of Health Care Products – Radiation- Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.* • *ISO 11137-2:2006, Sterilization of health care products – Radiation- Part 2: Establishing the sterilization dose* • *ISO 11137-3:2006, Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects* • *ISO 11607-1:2006, Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems*

[2] Hidron et al., Antimicrobial Resistant Pathogens Associated with Healthcare-Associated Infections: Annual Summary of Data Reported to the National Healthcare Safety Network at the Centers for Disease Control and Prevention, 2006-2007, *Infect Control Hosp Epidemiol* 2008; 29:996-1011.

Safety & Performance Tests Continued	• *ISO 11607-2:2006, Part 2: Validation Requirements for forming, sealing, and assembly processes* • *Draft Guidance for Industry and FDA – Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents* The subject device met all predetermined acceptance criteria derived from the above listed references and demonstrated substantially equivalent performance as compared to the cited predicate devices.
Summary of Substantial Equivalence	Based on the Indications for Use, technological characteristics, and safety and performance testing, the subject Site-Scrub IPA Device meets the requirements for its intended use and is as safe, as effective, and performs as well as or better than the predicate devices cited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Lynn M. Kirchoff
Associate Director, Regulatory Affairs
Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, Utah 84116

FEB 2 4 2012

Re: K112791
Trade/Device Name: Site-Scrub IPA Device
Regulation Number: None
Regulation Name: Pad, Alcohol, Device Disinfectant
Regulatory Class: Unclassified
Product Code: LKB
Dated: February 7, 2012
Received: February 9, 2012

Dear Ms. Kirchoff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112791

Device Name: Site-Scrub IPA Device

Indications for Use:

The Site-Scrub IPA Device is intended for use on injection ports and female luer hubs as a disinfecting cleaner.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR §801 Subpart D) (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

RLC Chapman 2/24/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112791